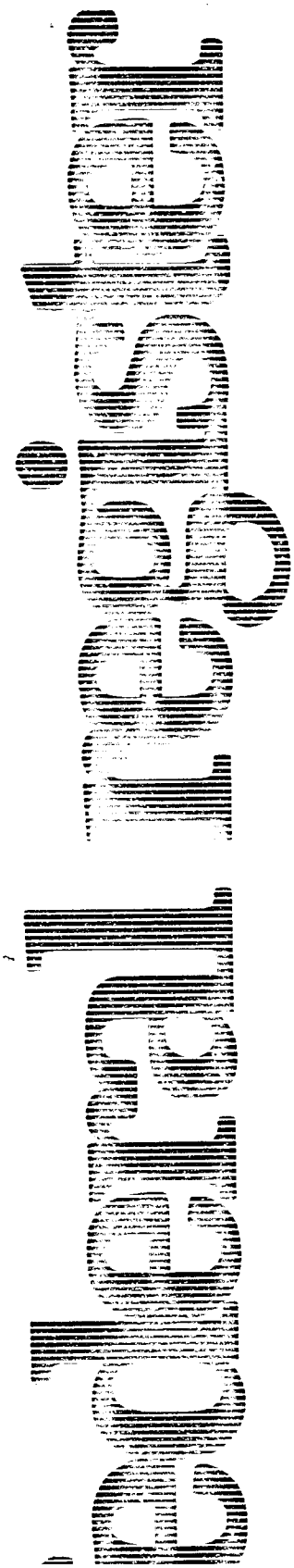

Wednesday
July 27, 1988

Part IV

Environmental Protection Agency

40 CFR Part 721

Significant New Use Rules; Amendments to General Provisions; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR PART 721

[OPTS-50527A; FRL-3357-1]

Significant New Use Rules; Amendments to General Provisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating amendments to the general provisions of 40 CFR Part 721, under the authority of section 5(a)(2) of the Toxic Substances Control Act (TSCA). The amendments clarify when manufacturers, importers, or processors must submit a significant new use notice and establish a procedure for obtaining EPA approval of alternative measures for control of human exposure and release to the environment that are the equivalent to those specified in a significant new use rule (SNUR). The amendments also establish a procedure for submission and review of significant new use notices during the proposal period of significant new use rules.

DATES: In accordance with 40 CFR 23.5 (50 FR 7271) this rule shall be promulgated for purposes of judicial review at 1 p.m. Eastern time on August 10, 1988. This rule shall become effective on September 9, 1988.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Acting Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. EB-44, 401 M Street SW., Washington, DC 20460, Telephone: (202) 554-1404, TDD: (202) 554-0551.

SUPPLEMENTARY INFORMATION: This rule amends the 40 CFR Part 721, Subpart A—General Provisions that apply to all SNURs. The provisions clarify when manufacturers, importers, or processors must submit a significant new use notice and establish a procedure for submission and review of significant new use notices during the proposal period of SNURs. The provisions also provide exemptions to the reporting requirements and establish a procedure under which the Agency may allow the use of alternative measures for control of human exposure and release to the environment that are equivalent to those specified in a SNUR.

The provisions in Part 721, Subpart A clarify existing general conditions under which recordkeeping and/or reporting may be required. The existing recordkeeping and reporting requirements are not significantly changed by the clarifications contained in this rule. Therefore, the Agency has determined that this clarifying rule does not impose any additional recordkeeping or reporting requirements on the public.

Send comments regarding this rule to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA."

I. Authority

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)), authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in section 5(a)(2). Once EPA determines a use to be a significant new use, persons must, under section 5(a)(1)(B) of TSCA, submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture, import, or process the substance for that use.

Persons subject to a SNUR must comply with the same regulations and procedures as persons who must submit a premanufacture notice (PMN) under section 5(a)(1)(A) of TSCA. In particular, these include the information submission requirements of sections 5 (b) and (d)(1), the exemptions authorized by sections 5(h) (1), (2), (3), and (5), and the regulations at 40 CFR Part 720. Once EPA receives a SNUN, the Agency may take regulatory action under sections 5(e), 5(f), 6, or 7 to control the activities on which it has received the notice. If EPA does not take action, section 5(g) requires the Agency to explain in the **Federal Register** its reasons for not taking action.

II. Summary of This Rule

This rule amends 40 CFR Part 721, Subpart A—General Provisions. Subpart A contains the general provisions that apply to all SNURs. The provisions set forth the requirements under which a manufacturer, importer, or processor must submit a SNUN to EPA. The provisions clarify who is responsible for reporting a significant new use and provide exemptions to the reporting requirements. The provisions also provide a procedure under which EPA may allow the use of alternative measures to control worker exposure to or environmental release of chemical substances. The amendments to 40 CFR Part 721, Subpart A—General Provisions are listed below:

1. Certain sections are renumbered and applicable cross references are changed.

2. A manufacturer, importer, or processor is not required to submit a SNUN if such person can document one or more of the following for each recipient of a substance subject to a SNUR:

(a) The recipient has been provided with notice of the SNUR.

(b) The recipient knows of the SNUR.

(c) It is technically or otherwise not feasible for the recipient to engage in the significant new use.

3. A manufacturer, importer, or processor who intends to distribute a chemical substance subject to a SNUR to a recipient for nonexempt purposes, and has prior knowledge that the recipient intends to engage in a significant new use of that substance without submitting a SNUN, must submit a SNUN to EPA before distributing that chemical substance to that recipient.

4. A manufacturer, importer, or processor who is distributing a chemical substance subject to a SNUR to a recipient, and obtains knowledge that the recipient is engaging in a significant new use and has not submitted a SNUN to EPA, must immediately cease distribution of the chemical substance to that recipient and submit a SNUN, unless: (a) It can document that it has notified (within 15 working days of the time it develops knowledge that the recipient is engaging in a significant new use) the recipient and EPA in writing of the significant new use, and (b) the recipient has informed the manufacturer, importer, or processor, within 15 working days, in writing, that it will not engage in the significant new use. A copy of the recipient's reply must be sent to EPA enforcement authorities.

5. Provisions for the TSCA section 5(h)(3) research and development (R&D) exemption are added which mirror the R&D exemption in the PMN rule (40 CFR 720.36; April 22, 1986, 51 FR 15096).

6. A procedure is established whereby a person may obtain EPA approval to manufacture or process a chemical substance for a significant new use before the promulgation date of the final SNUR. Under this advanced compliance exemption, EPA will accept and review SNUNs during the proposal period.

7. A procedure is established under which EPA may allow use of alternative measures to control exposure to, or environmental release of, a chemical substance without submitting a SNUN, if EPA determines that the alternative measures provide substantially the same degree of protection as the control

methods specified in the SNUR for the chemical substance.

8. An exemption is established whereby persons operating under and abiding by the terms of a consent order issued under section 5(e) of the Act will be exempt from submitting a SNUN under provisions which are inconsistent.

III. Background

On September 5, 1984 (49 FR 35001), the Agency promulgated at 40 CFR Part 721, Subpart A—General Provisions that apply to all SNURs. Subsequent to promulgation of these provisions, the Agency received comments on certain sections of the promulgated rule. On April 22, 1986 (51 FR 15104), EPA proposed amendments to the general provisions. EPA received comments from industry and environmental groups on the proposed amendments. After consideration of these comments, 40 CFR Part 721, the Subpart A—General Provisions are being published in final form. On April 22, 1986, amendments were proposed for the following sections: §§ 721.180, 721.290, 721.615, and 721.975. These amendments are not being promulgated at this time but will be amended as part of the overall review of SNURs. EPA also had proposed a new Subpart which would set forth hazard communication program for persons subject to SNURs. The hazard communication program will also be promulgated at a later date.

IV. Amendments

A. Persons Who Must Report

Section 721.5 describes who must submit a SNUN. The provisions promulgated on September 5, 1984, required each person who intended to manufacture, import, or process a chemical substance subject to a SNUR and intended to distribute the substance in commerce to submit a SNUN. However, persons subject to § 721.5 did not have to submit a SNUN if they: (1) Did not have a reasonable belief at the time of commercial distribution that a customer intended to engage in a signficant new use without submitting a notice to EPA, and (2) were able to document that the customer was notified in writing of the SNUR.

The Agency received comments requesting clarification of the responsibility of manufacturers, importers, and processors to submit SNUNs as specified under the provisions of section 5(a)(1)(B) of TSCA and § 721.5(a)(2). This final rule amends § 721.5 so that persons subject to paragraph (a)(2) do not have to submit a SNUN if they can document for each recipient of the substance one or more of the following:

(1) They have provided the recipient with notice of the SNUR.

(2) The recipient knows of the SNUR.

(3) It is technically or otherwise infeasible for the recipient to engage in the significant new use.

A comment received on the proposed amendment expressed concern that EPA should clarify the scope of the requirement to notify "recipients." At issue was whether the rule would require manufacturers, importers, or processors to notify persons who purchase the SNUR substance from their customers or competitors. The commenter argued that it would be extremely difficult to identify and contact all such "recipients." The commenter suggested the Agency either substitute the term "customer" for "recipient," or define the term "recipient." To address this comment, the term "recipient" has been specifically defined in the final rule in § 721.3. The Agency intends that the "recipient" is a person who obtains the substance directly from the manufacturer, importer, or processor. If the recipient is also a process of the substance, it would in turn have the same obligation with respect to recipients.

Another commenter suggested that the Agency delete § 721.5(d) under which manufacturers and processors must terminate sales to recipients and inform EPA if they learn that the recipients are engaging in a significant new use. The commenter argued that the requirements are not authorized by TSCA, that they have the potential to unnecessarily disrupt ongoing commercial activities and business relationships, and that the requirement to cease distribution to the recipient until after a SNUN has been submitted and reviewed is extremely harsh. The alternative suggested by the commenter was that manufacturers and processors would document all instances of noncompliance with SNUR provisions and work with customers to prevent a recurrence of significant new use violations. Where serious or repeated violations come to the manufacturer's, importer's, or processor's attention, they would have the option of either terminating sales or notifying EPA. In the latter event, the Agency would determine whether sales to the recipient should be suspended.

Under TSCA section 5, EPA has the responsibility to require compliance with SNUR provisions and cannot delegate that responsibility to private citizens. However, to avoid unnecessary commercial disruption, the Agency is amending § 721.5(d) to allow the manufacturer, importer, or processor an opportunity to work with its customer/recipient if the manufacturer, importer, or processor finds that that person is engaging in a significant new use without having submitted a SNUN. Under the revised § 721.5(d), the manufacturer, importer, or processor must notify (within 15 working days of the time he/she develops knowledge that the recipient is engaging in a significant new use) in writing the recipient and EPA that the recipient is engaging in a significant new use. If, within 15 working days, the recipient states in writing the he/she will not engage in the significant new use, commercial distribution to that person may continue uninterrupted. EPA enforcement authorities will check the recipient's actions to ensure that the significiant new use is not occurring. If upon inspection the Agency determines a significant new use is occurring, EPA will then determine whether a SNUN must be submitted. It may be that EPA can work with the recipient to bring him/her into compliance. If the recipient does not come into compliance quickly, EPA will notify the manufacturer, importer, or processor. Upon receipt of this notice, the manufacturer, importer, or processor will be required to cease distribution to that recipient and will not be able to resume such distribution until the manufacturer, importer, or processor submits a SNUN and the notice review period ends. Similarly, if, after receiving a written assurance from a recipient, the manufacturer, importer, or processor determines on its own that the recipient is engaging in a significant new use without submitting a SNUN, the manufacturer, importer, or processor is required to cease distribution to that recipient immediately and to notify EPA enforcement authorities. In that case also, such distribution could not resume until the manufacturer, importer, or processor has submitted a SNUN and the notice review period has ended. Independent of these provisions EPA reserves the right to take an enforcement action against any recipient which is a processor who has violated a SNUR.

Finally, a commenter argued that if EPA insists upon retaining rigid recipient termination requirements it should clarify when "knowledge" occurs. The commenter argued that such knowledge should be imputed to a company only if it comes to the attention of responsible officials capable of appreciating its significance and that it is unrealistic to expect salespersons and other non-regulatory employees to

identify and report deviations from SNUR requirements.

EPA intends to use discretion to enforce § 721.5. A company will be considered to have "knowledge" that a recipient is engaging in a significant new use when an employee of the company, who by the nature of position or responsibility within the company should have knowledge of the SNUR provisions, becomes aware that the recipient is engaging in the significant new use.

B. Equivalency Determination

Some SNURs designate manufacturing, processing, or use without specified control measures as a significant new use. The Agency received comments indicating that manufacturers, importers, and processors would like the flexibility to choose the type of protective controls to use for employee exposure and environmental release. The commenters argue that the Agency should either set permissible exposure limits or performance based standards, and should not require specific types of personal protective equipment. While the Agency is interested in developing permissible exposure levels, such limits have not yet been developed and are not within the scope of this rulemaking.

The Agency also received comments that its practice of specifying respirator requirements is in conflict with the Occupational Safety and Health Administration policy that requires engineering controls be used where feasible. To address this problem, the Agency is adding a procedure in new § 721.30 which will allow manufacturers, importers, and processors to propose alternative control measures for human exposure and environmental release. EPA will review the proposed alternative control measures and make a determination whether they provide substantially the same degree of protection as the measures specified in the SNUR. The procedure allows manufacturers, importers, and processors to use work practices or engineering controls rather than specific devices like respirators to control exposure.

Commenters favored the equivalency provision, but questioned whether too much substantiation was required for such a finding. EPA has made the equivalency determination procedures as simple as possible. Section 721.30 requires persons to demonstrate that their intended activities will provide substantially the same degree of protection to health and the environment as the measures identified in a SNUR. The Agency will review and make a determination upon such requests within 45 days. EPA view the requirements as reasonable and in the public interest. The alternative is for persons to submit a SNUN and wait 90 days for EPA review.

C. Research and Development Exemption

This rule specifies requirements for the R&D exemption from SNURs under section 5(h)(3) of TSCA. The R&D exemption requirements established by this rule are essentially the same as the R&D provisions in the PMN rule. Section 5(h)(3) of TSCA exempts from the PMN and significant new use notification requirements small quantities of a substance used solely for R&D, if the manufacturer, importer, or processor notifies persons engaged in the R&D of any health effects associated with the substance.

Section 721.47 was drawn without substantive changes from the R&D exemption provisions in the PMN rule. It is codified separately for SNURs rather than referenced in Part 721 to revise the exemption slightly to reflect SNUR requirements. Because of the similar nature of PMN and SNUR requirements, EPA believes it is important that the R&D exemption for PMNs and SNURs be consistent. Therefore, any substantive change in the SNUR exemption would require an equivalent change in the PMN rule. As part of the April 22, 1986 promulation, EPA determined through notice and comment rulemaking that the benefits of the provisions for the R&D exemption in the PMN rule outweight the potenital disadvantages. This conclusion is also valid for the R&D exemption requirements in § 721.47.

D. Exemptions

1. Applicability of Proposed Rule to Uses Occurring Before Promulation of Final Rule

In the preambles to previously proposed SNURs, the Agency has stated that section 5(a)(1)(b) of TSCA is best served by determining that a use is a significant new use as of the date of proposal. This interpretation of section 5 reflects the intent of Congress with regard to SNURs; if uses begun during the proposal period of the SNUR were not considered to be significant new uses, it would be difficult for the Agency to establish SNUN requirements because any person could defeat the SNUR by initiating a proposed significant new use before the rule became final.

A person may legally commence an activity designated as a significant new use in a proposed SNUR. If that person wishes to continue the activity after the SNUR is promulgated and becomes effective, they must stop, file a SNUN, and wait for EPA review of the notice before resuming the activity (assuming the Agency has not taken action under section 5(e) or 5(f) of TSCA). However, it is not the intent of the Agency to unnecessarily disrupt the commercial activities of these persons. EPA therefore proposed that such persons be allowed to comply with a SNUR before the rule is promulgated. If a company were to meet all of the conditions of advance compliance, as specified in the new § 721.45(h) (proposed as § 721.18(h)) the person will be exempt from the requirements of the final SNUR for those activities. It should be emphasized that EPA intends to use its full TSCA authority to control the company's activities, should the Agency determine that such activities will present an unreasonable risk of injury to human health or the environment.

The first requirement for advance compliance with a SNUR is to submit a complete SNUN to EPA. The notice must contain all requisite SNUR data, with limitations described in the applicable proposed SNUR. Any person who submits and advance SNUN for a subject chemical substance will be subject to the general notification requirements of § 721.25, except that the company will not have to submit the notice to the Agency at least 90 days before it begins manufacturing, importing, or processing. However, should the final SNUR be promulgated prior to completion of the Agency's review, the company will be required to cease manufacturing, importing, or processing for the remaining portion of the 90-day period.

A commenter was concerned that voluntary SNUN submitters (i.e., persons using the advance compliance exception) may have to cease manufacturing, importing, or processing for the significant new use if the effective date of the final SNUR occurs before the Agency's 90-day review of the voluntarily submitted notice is complete. The commenter suggested that EPA delay the effective date of all SNURs until 90 days after publication to allow EPA to complete its review of notices voluntarily submitted at any time prior to the promulation date without a disruption of the commercial activities of those notice submitters.

EPA is aware that, should the final SNUR be promulated and become effective prior to completion of the Agency's review, the person would be required to cease manufacturing,

importing, or processing for the remaining portion of the 90-day review period. While EPA wants to keep commercial disruption to a minimum and is aware of the fact that the events described by the commenter are possible, the Agency's primary responsibility under TSCA section 5(a)(2) is to develop SNURs quickly and ensure that no significant new uses occur until EPA has reviewed the uses and taken appropriate action. If the Agency were to routinely delay the effective date of all SNURs it would set up a situation where uses involving potentially significant levels of exposure or environmental release could go on even longer before they could be controlled under a SNUR. The Agency wishes to balance its concern for exposure and release with its concern for regulatory impact.

As a matter of policy, EPA favors and will continue to use a short time period between the promulgation and effective dates of minor rules such as SNURs. The Agency believes that the approach adopted in this final rule provides sufficient time for completion of the review period for voluntary SNUNs submitted in a timely manner (e.g., 90 days before the effective date). EPA will inform voluntary submitters of the possibility that the final SNUR will be promulagated and in effect before Agency review of their SNUN is completed. This will allow these persons adequate time to plan their activities accordingly. Agency review of voluntary SNUNs will be completed as quickly as possible (up to 90 days) to minimize potential disruption of the submitter's commercial activities.

2. Section 5(e) Consent Order Exemption

The Agency has added an exemption in § 721.45(i) for persons operating under the terms of a TSCA section 5(e) consent order. If a term of a section 5(e) order applicable to that person is inconsistent with a specific significant new use identified in Subpart E of the part, abiding by the terms of the section 5(e) consent order will exempt the person from submitting a SNUN for that significant new use.

V. Economic Analysis

Promulgation of these amendments will result in costs to both EPA and industry. However, as will be addressed below, the costs are not expected to be more than without this final rule, and in some cases may be less. Where quantification is possible, the costs associated with each final amendment are discussed. In some cases, only a qualitative discussion is possible. The costs of the relevant sections of previously proposed SNURs (in the absence of the final amendments) are also discussed.

1. *Section 721.5 Persons who must report.* Companies involved in the manufacture, import, or processing of a SNUR substance will incur costs of compliance with this section. The costs can range from those costs associated with a letter notifying a recipient of the existence of the SNUR, up to the costs of submitting a SNUN ($1,400 to $8,000). Additional costs of filing a SNUN may be incurred (up to a 3.2 percent reduction in profits due to delays in manufacturing or processing for Agency review) and EPA costs of regulatory follow-up, if any.

The actual costs of notifying recipients of the existence of a SNUR are expected to be minimal, for example, the cost of sending a letter to each recipient. The Agency believes that most companies will choose to document that recipients know of the rule via a notification letter as it is the least costly alternative.

2. *Section 721.30 Equivalency determination.* Based on comments to proposed SNURs which would require reporting for failure to employ specific worker exposure or environmental release controls, the Agency believes that most companies seeking an equivalency determination will either possess or be able to covert to the alternative provisions or measures for which they are seeking an equivalency determination. In the absence of this amendment, such companies would either have to submit a SNUN ($1,400 to $8,000 per SNUN, plus up to 3.2 percent reduction in profits) and/or incur the cost of complying with the controls or measures as specified in the SNUR.

The costs to companies of this amendment will be the development costs of the data submitted to the Agency. This consists of a written justification that the alternative provisions provide at least the same degree of protection. The Agency cannot estimate the exact equivalency development costs at this time. Other costs associated with the equivalency determination involve filing the request for equivalency determination, and delay costs during Agency review. The Agency expects the costs of filing the equivalency notice to be equal to or less than the costs of filing a SNUN, since the information required in a request for equivalency determination is less than that required in a SNUN. In addition, any potential loss in profits due to delays associated with Agency review would be less. Delay costs are estimated to be a 3.2 percent reduction in profits due to delays in manufacturing and processing during the 90-day Agency review of SNUNs. Delay costs associated with an equivalency determination would be half of the delay costs for a SNUN, or a 1.6 percent reduction in profits due to delays during the 45-day Agency review.

Therefore, while the Agency cannot quantity the exact costs, the total costs are expected to be less for an equivalency determination than for submitting a SNUN.

3. *Section 721.45(h) Advance compliance exemption.* The procedures for advance compliance are generally the same as for any SNUN. The manufacturer, importer, or processor must submit a complete SNUN. The costs to the company for filing a SNUN are estimated to be between $1,400 and $8,000. However, this notice need not be submitted 90 days prior to commencing manufacture, import, or processing but can be submitted anytime between proposal and promulgation of the SNUR.

The major difference is that if the Agency negotiates with the company to control or limit the significant new use, or does not ban the chemical substance, the company can continue production of the chemical substance without interruption when the SNUR is promulgated, thereby avoiding any loss in profits usually attributed to delays in manufactuing or processing during Agency review. However, if the Agency's 90-day review of the SNUN is not completed by the effective date of the final SNUR, all significant new use activities must cease for the remaining portion of the review period.

VI. Rulemaking Record

EPA has established a record for this rulemaking (docket control number OPTS-50527A). The record includes basic information considered by the Agency in developing this final rule. EPA will supplement the record with additional information as necessary, and will identify the complete rulemaking record by the date of promulgation. A public version of this record containing sanitized copies from which Confidential Business Information (CBI) has been deleted is available to the public in the TSCA Public Docket Office from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays. The TSCA Public Docket Office is located in Rm. NE-G004, 401 M St., SW., Washington, DC.

The record includes the following:

1. The proposed rule.
2. Public comments.
3. Response to comment document.
4. This final rule.

5. The economic analysis of this final rule.

VII. Regulatory Assessment Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a rule is "major" and therefore, requires a Regulatory Impact Analysis. EPA has determinated that this final rule is not a "major rule" because it will not have an effect on the economy of $100 million or more, and it will not have a significant effect on competition, costs, or prices. While there is no precise way to calculate the total annual cost of compliance with this final rule, for the reasons discussed in this preamble, EPA believes that the cost will be low.

This rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 605(b), EPA has determined that this final rule will not have a significant impact on a substantial number of small businesses. The Agency cannot determine whether parties affected by this final rule are likely to be small businesses. However, EPA believes that the number of small businesses affected by this final rule will not be substantial even if all the potential new uses were developed by small companies.

C. Paperwork Reduction Act

The information collection requirements contained in Subpart A have been approved by OMB under the provisions of the *Paperwork Reduction Act*, 44 U.S.C. 3501 *et seq.* and have been assigned OMB control number (2070–0012).

The provisions in Part 721, Subpart A clarify existing general conditions under which recordkeeping and/or reporting may be required. The existing recordkeeping and reporting requirements are not significantly changed by the clarifications contained in this rule. Therefore, the Agency has determined that this clarifying rule does not impose any additional recordkeeping or reporting requirements on the public.

Send comments regarding this rule to Chief, Information Policy Branch, PM–223, U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA."

List of Subjects in 40 CFR Part 721

Chemicals, Environmental protection, Hazardous substances, Recordkeeping and reporting requirements, Significant new uses.

Dated: July 6, 1988.

Lee M. Thomas,

Administrator.

Therefore, 40 CFR Part 721 is amended as follows:

PART 721—[AMENDED]

1. The authority citation for Part 721 continues to read as follows:

Authority: 15 U.S.C. 2604 and 2607.

2. Section 721.1 is revised to read as follows:

§ 721.1 Scope and applicability.

(a) This part identifies uses of chemical substances which EPA has determined are significant new uses under the authority of section 5(a)(2) of the Toxic Substances Control Act. In addition, it specifies procedures for manufacturers, importers, and processors to report on those significant new uses. This subpart A contains general provisions applicable to this part. Subpart B of this part identifies generic requirements for certain significant new uses cross referenced in specific provisions of Subpart E of this part. Subpart C of this part identifies generic reporting requirements for certain significant new uses cross referenced in specific provisions of Subpart E of this part. Subpart E of this part identifies chemical substances and their significant new uses.

(b) This Subpart A contains provisions governing submission and review of notices for the chemical substances and significant new uses identified in Subpart E of this part. The provisions of this Subpart A apply to the chemical substances and significant new uses identified in Subpart E of this part, except to the extent that they are specifically modified or supplanted by specific requirements in Subpart E of this part. In the event of a conflict between the provisions of this Subpart A and the provisions of Subpart E of this part, the provisions of Subpart E of this part shall govern.

(c) The provisions of Part 720 of this Chapter apply to this Part 721. For purposes of this Part 721, wherever the phrase "new chemical substance" appears in Part 720 of this chapter, it shall mean the chemical substance subject to this Part 721. In the event of a conflict between the provisions of Part 720 of this chapter and the provisions of this Part 721, the provisions of this Part 721 shall govern.

3. Section 721.3 is revised to read as follows:

§ 721.3 Definitions.

The definitions in section 3 of the Act, 15 U.S.C. 2602, and § 720.3 of this chapter apply to this part. In addition, the following definitions apply to this part:

"CAS Number" means Chemical Abstracts Service Registry Number assigned to a chemical substance on the Inventory.

"Customer" means any person to whom a manufacturer, importer, or processor distributes any quantity of a chemical substance, or of a mixture containing the chemical substance, whether or not a sale is involved.

"Metalworking fluid" means a liquid of any viscosity or color containing intentionally added water and used in metal machining operations for the purpose of cooling, lubricating, or rust inhibition.

"Powder or dry solid form" means a state where all or part of the substance would have the potential to become fine, loose, solid particles.

"Principal importer" means the first importer who, knowing that a chemical substance will be imported for a significant new use rather than manufactured in the United States, specifies the chemical substance and the amount to be imported. Only persons who are incorporated, licensed, or doing business in the United States may be principal importers.

"Process for commercial purposes" means the preparation of a chemical substance or mixture containing the chemical substance, after manufacture of the substance, for distribution in commerce with the purpose of obtaining an immediate or eventual commercial advantage for the processor. Processing of any amount of a chemical substance or mixture containing the chemical substance is included in this definition. If a chemical substance or mixture containing impurities is processed for commercial purposes, the impurities also are processed for commercial purposes.

"Process solely for export" means to process for commercial purposes solely for export from the United States under the following restrictions on activity in the United States: Processing must be performed at sites under the control of the processor; distribution in commerce is limited to purposes of export; and the processor may not use the chemical substance except in small quantities solely for research and development.

"Recipient" means any person who purchases or otherwise obtains a

chemical substance directly from a person who manufacturers, imports, or processes the substance.

"Site" means a contiguous property unit. Property divided only by a public right-of-way is one site. There may be more than one manufacturing plant on a single site.

"Site-limited intermediate" means an intermediate manufactured, processed, and used only within a site and not distributed in commerce other than as an impurity or for disposal. Imported intermediates cannot be "site-limited."

"Spray application" means any method of projecting a jet of vapor of finely divided liquid onto a surface to be coated; whether by compressed air, hydraulic pressure, electrostatic forces, or other methods of generating a spray.

"Waters of the United States" has the meaning set forth in 40 CFR 122.2.

4. Section 721.5 is revised to read as follows:

§ 721.5 Persons who must report.

(a) The following persons must submit a significant new use notice as specified under the provisions of section 5(a)(1)(B) of the Act, Part 720 of this chapter, and § 721.25:

(1) A person who intends to manufacture, import, or process for commercial purposes a chemical substance identified in a specific section in Subpart E of this part, and intends to engage in a significant new use of the substance identified in that section.

(2) A person who intends to manufacture, import, or process for commercial purposes a chemical substance identified in a specific section in Subpart E of this part, and intends to distribute the substance in commerce. A person described in this paragraph is not required to submit a significant new use notice if that person can document one or more of the following as to each recipient of the substance from that person:

(i) That the person has notified the recipient, in writing, of the specific section in Subpart E of this part which identifies the substance and its designated significant new uses.

(ii) That the recipient has knowledge of the specific section in Subpart E of this part which identifies the substance and its designated significant new uses.

(iii) That the recipient cannot undertake any significant new use described in the specific section in Subpart E of this part.

(b) A person described in paragraph (a)(2) of this section must submit a significant new use notice if that person has knowledge at the time of commercial distribution of the substance identified in the specific section in Subpart E of this part that a recipient intends to engage in a designated significant new use of that substance without submitting a notice under this part.

(c) A person who processes a chemical substance identified in a specific section in Subpart E of this part for a significant new use of that substance is not required to submit a significant new use notice if that person can document each of the following:

(1) That the person does not know the specific chemical identity of the chemical substance being processed.

(2) That the person is processing the chemical substance without knowledge that the substance is identified in Subpart E of this part.

(d)(1) If at any time after commencing distribution in commerce of a chemical substance identified in a specific section in Subpart E of this part a person described in paragraph (a)(2) of this section has knowledge that a recipient of the substance is engaging in a significant new use of that substance designated in that section without submitting a notice under this part, the person is required to cease supplying the chemical substance to that recipient and to submit a significant new use notice for that chemical substance and significant new use, unless the person is able to document each of the following:

(i) That the person has notified the recipient and EPA enforcement authorities (at the address in paragraph (d)(1)(iii) of this section), in writing within 15 working days of the time the person develops knowledge that the recipient is engaging in a significant new use, that the recipient is engaging in a significant new use without submitting a significant new use notice.

(ii) That, within 15 working days of notifying the recipient as described in paragraph (d)(1)(i) of this section, the person received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of the applicable section in Subpart E of this part and will not engage in the significant new use.

(iii) That the person has promptly provided EPA enforcement authorities with a copy of the recipient's statement of assurance described in paragraph (d)(1)(ii) of this section. The copy must be sent to the Director, Office of Compliance Monitoring (EN-342), Environmental Protection Agency, 401 M St. SW., Washington, DC 20460.

(2) If EPA notifies the manufacturer, importer, or processor that the recipient is engaging in a significant new use after providing the statement of assurance described in paragraph (d)(1)(ii) of this section and without submitting a notice under this part, the manufacturer, importer, or processor shall immediately cease distribution to that recipient until the manufacturer, importer, or processor or the recipient has submitted a significant new use notice under this part and the notice review period has ended.

(3) If, after receiving a statement of assurance from a recipient under paragraph (d)(1)(ii) of this section, a manufacturer, importer, or processor has knowledge that the recipient is engaging in a significant new use without submitting a notice under this part, the manufacturer, importer, or processor must immediately cease distributing the substance to that recipient and notify EPA enforcement authorities at the address identified in paragraph (d)(1)(iii) of this section. The manufacturer, importer, or processor may not resume distribution to that recipient until any one of the following has occurred:

(i) The manufacturer, importer, or processor has submitted a significant new use notice under this part and the notice review period has ended.

(ii) The recipient has submitted a significant new use notice under this part and the notice review period has ended.

(iii) The manufacturer, importer, or processor has received notice from EPA enforcement authorities that it may resume distribution to that recipient.

(e) Any significant new use notice relating to import of a substance must be submitted by the principal importer.

§ 721.6 [Redesignated as § 721.11]

5. Section 721.6 is redesignated as § 721.11, and the entire section is revised to read as follows:

§ 721.11 Applicability determination when the specific chemical identity is confidential.

(a) A person who intends to manufacture, import, or process a chemical substance which is described by a generic chemical name is Subpart E of this part may ask EPA whether the substance is subject to the requirements of this part. EPA will answer such an inquiry only if EPA determines that the person has a *bona fide* intent to manufacture, import, or process the chemical substance for commercial purposes.

(b) To establish a *bona fide* intent to manufacture, import, or process a chemical substance, the person who intends to manufacture, import, or process the chemical substance must submit the following information in writing to the Office of Toxic Substances, Document Control Officer,

TS–790, 401 M St. SW., Washington, DC 20460: ATTN: SNUR *bona fide* submission.

(1) The specific chemical identity of the chemical substance that the person intends to manufacture, import, or process.

(2) A signed statement that the person intends to manufacture, import, or process the chemical substance for commercial purposes.

(3) A description of the research and development activities conducted to date, and the purpose for which the person will manufacture, import, or process the chemical substance.

(4) An elemental analysis.

(5) Either an X-ray diffraction pattern (for inorganic substances), a mass spectrum (for most other substances), or an infrared spectrum of the particular chemical substance, or, if such data do not resolve uncertainties with respect to the identity of the chemical substance, additional or alternative spectra or other data to identify the substance.

(c) If an importer or processor cannot provide all the information required in paragraph (b) of this section because it is claimed as confidential business information by the importer's or processor's manufacturer or supplier, the manufacturer or supplier may supply the information directly to EPA.

(d) EPA will review the information submitted by the manufacturer, importer, or processor under paragraph (b) of this section to determine whether than person has shown a *bona fide* intent to manufacture, import, or process the chemical substance. If necessary, EPA will compare this information either to the information requested for the confidential chemical substance under § 710.7(e)(2)(v) of this chapter or the information requested under § 720.85(b)(3)(iii) of this chapter.

(e) If the manufacturer, importer, or processor has shown a *bona fide* intent to manufacture, import, or process the substance and has provided sufficient unambiguous chemical identity information to enable EPA to make a conclusive determination as to the identity of the substance, EPA will inform the manufacturer, importer, or processor whether the chemical substance is subject to this part and, if so, which section in Subpart E of this part applies.

(f) A disclosure to a person with a *bona fide* intent to manufacture, import, or process a particular chemical substance that the substance is subject to this part will not be considered public disclosure of confidential business information under section 14 of the Act.

(g) EPA will answer an inquiry on whether a particular chemical substance is subject to this part within 30 days after receipt of a complete submission under paragraph (b) of this section.

§ 721.7 [Redesignated as § 721.20]

6. Section 721.7 is redesignated as § 721.20, and the entire section is revised to read as follows:

§ 721.20 Exports and Imports.

Persons who intend to export a chemical substance identified in Subpart E of this part, or in any proposed rule which would amend Subpart E of this part, are subject to the export notification provisions of section 12(b) of the Act. The regulations that interpret section 12(b) appear at 40 CFR Part 707. Persons who import a substance identified in a specific section in Subpart E of this part are subject to the import certification requirements under section 13 of the Act, which are codified at 19 CFR 12.118 through 12.127 and 127.28. The EPA policy in support of the import certification requirements appears at 40 CFR Part 707.

§ 721.10 [Redesignated as § 721.25]

7. Section 721.10 is redesignated as § 721.25, and the entire section is revised to read as follows:

§ 721.25 Notice requirements and procedures.

(a) Each person who is requuired to submit a significant new use notice under this part must submit the notice at least 90 calendar days before commencing manufacture, import, or processing of a chemical substance identified in Subpart E of this part for a significant new use. The submitter must comply with any applicable requirement of section 5(b) of the Act, and the notice must include the information and test data specified in section 5(d)(1) of the Act. The notice must be submitted on the notice from in Appendix A to Part 720 of this chapter and must comply with the requirements of Part 720, except to the extent that they are inconsistent with this Part 721.

(b) If two or more persons are required to submit a significant new use notice for the same chemical substance and significant new use identified in Subpart E of this part, they may submit a joint notice to EPA. Persons submitting a joint notice must individually complete the certification section of Part I of the required notification form. Persons who are required to submit individually, but elect to submit jointly, remain individually liable for the failure to submit required information which is known to or reasonably ascertainable by them and test data in their possession or control.

(c) EPA will process the notice in accordance with the procedures of Part 720 of this chapter, expect to the extent they are inconsistent with this Part 721.

(d) Any person submitting a significant new use notice in response to the requirements of this Part 721 shall not manufacture, import, or process a chemical substance identified in Subpart E of this part for a significant new use until the notice review period, including all extensions and suspensions, has expired.

8. By adding a new § 721.30 to read as follows:

§ 721.30 EPA approval of alternative control measures.

(a) In certain sections of Subpart E of this part, significant new uses for the identified substances are described as the failure to establish and implement programs providing for the use of either: specific measures to control worker exposure to or release of substances which are identified in such sections, or alternative measures to control worker exposure or environmental release which EPA has determined provide substantially the same degree of protection as the specified control measures. Persons who manufacture, import, or process a chemical substance identified in such sections and who intend to employ alternative measures to control worker exposure or environmental release must submit a request to EPA for a determination of equivalency before commencing manufacture, import, or processing involving the alternative control measures.

(b) A request for a determination of equivalency must be submitted in writing to the Office of Toxic Substances, Document Control Officer, TS–790, 401 M St. SW., Washington, DC 20460: ATTN: SNUR Equivalency Determination, and must contain:

(1) The name of the submitter.

(2) The specific chemical identity of the substance.

(3) The citation for the specific section in Subpart E of this Part which pertains to the substance for which the request is being submitted.

(4) A detailed description of the activities involved.

(5) The specifications of the alternative worker exposure control measures or environmental release control measures.

(6) An analysis justifying why such alternative control measures provide substantially the same degree of protection as the specific control measures identified in the specific section in Subpart E of this part which

pertains to the substance for which the request is being submitted.

(7) The data and information described in §§ 720.50 (a) and (b) of this chapter unless such data and information have already been submitted to the Office of Toxic Substances, EPA.

(c) Requests for determinations of equivalency will be reviewed by EPA within 45 days. Determinations under this paragraph will be made by the Director, Office of Toxic Substances, or designee. Notice of the results of such determinations will be mailed to the submitter.

(d) If EPA notifies the submitter under paragraph (c) of this section that EPA has determined that the alternative control measures provide substantially the same degree of protection as the specified control measures identified in the specified section of Subpart E of this part which pertains to the substance for which the request is being submitted, the submitter may commence manufacture, import, or processing in accordance with the specifications for alternative worker exposure control measures or environmental release control measures identified in the submitter's request, and may alter any corresponding notification to workers to reflect such alternative controls. Deviations from the activities described in the EPA notification constitute a significant new use and are subject to the requirements of this part.

§ 721.13 [Redesignated as § 721.35]

9. Section 721.13 is redesignated as § 721.35, and the entire section is revised to read as follows:

§ 721.35 Compliance and enforcement.

(a) Failure to comply with any provision of this part is a violation of section 15(1) of the Act (15 U.S.C. 2614).

(b) Using for commercial purposes a chemical substance which a person knew or had reason to know was manufactured, imported, or processed in violation of this part is a violation of section 15(2) of the Act (15 U.S.C. 2614).

(c) Failure or refusal to permit access to or copying of records, as required by section 11 of the Act, is a violation of section 15(3) of the Act (15 U.S.C. 2614).

(d) Failure or refusal to permit entry or inspection, as required by section 11 of the Act, is a violation of section 15(4) of the Act.

(e) Violators of the Act or of this part may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation. The submission of false or misleading information in connection with the requirement of any provision of this part may subject persons to penalties calculated as if they never filed a notice.

(f) Under the authority of sections 7 and 17 of the Act, EPA may:

(1) Seek to enjoin the manufacture, import, or processing of a chemical substance in violation of this part.

(2) Act to seize any chemical substance which is being manufactured, imported, or processed in violation of this part.

(3) Take any other appropriate action.

10. Section 721.17 is redesignated as § 721.40, and the entire section is revised to read as follows:

§ 721.40 Recordkeeping.

Any person subject to the requirements of this part must retain documentation of information contained in that person's significant new use notice. This documentation must be maintained for a period of 5 years from the date of the submission of the significant new use notice.

§ 721.19 [Redesignated as § 721.45]

11. Section 721.19 is redesignated as § 721.45, and the entire section is revised to read as follows:

§ 721.45 Exemptions.

The persons identified in § 721.5 are not subject to the notification requirements of § 721.25 for a chemical substance identified in Subpart E of this part, unless otherwise specified in a specific section in Subpart E, if:

(a) The person has applied for and has been granted an exemption for test marketing the substance for a significant new use identified in Subpart E of this part in accordance with section 5(h)(1) of the Act and § 720.38 of this chapter.

(b) The person manufactures, imports, or processes the substance for a significant new use identified in Subpart E of this part in small quantities solely for research and development in accordance with § 721.47.

(c) The person has applied for and been granted an exemption under section 5(h)(5) of the Act.

(d) The person manufactures, imports, or processes the substance only as an impurity.

(e) The person manufactures, imports, or processes the substance only as a byproduct which is used only by public or private organizations that (1) burn it as a fuel, (2) dispose of it as a waste, including in a landfill or for enriching soil, or (3) extract component chemical substances from it for commercial purposes.

(f) The person imports or processes the substance as part of an article.

(g) The person manufactures or processes the substance solely for export and, when distributing the substance in commerce, labels the substance in accordance with section 12(a)(1)(B) of the Act.

(h) The person submits a significant new use notice for the substance prior to the promulgation date of the section in Subpart E of this part which identifies the substance, and the person receives written notification of compliance from EPA prior to the effective date of such section. The notice submitter must comply with any applicable requirement of section 5(b) of the Act. The notice must include the information and test data specified in section 5(d)(1) of the Act and must be submitted on the notice form in Appendix A to Part 720 of this chapter. For purposes of this exemption, the specific section in Subpart E of this part which identifies the substance and §§ 721.1, 721.3, 721.11, 721.35, and 721.40 apply; after the effective date of the section in Subpart E of this part which identifies the substance, § 721.5 applies and § 721.20 continues to apply. EPA will provide the notice submitter with written notification of compliance only if one of the following occurs:

(1) EPA is unable to make the finding that the activities described in the significant new use notice will or may present an unreasonable risk of injury to health or the environment under reasonably foreseeable circumstances.

(2) EPA and the person negotiate a consent order under section 5(e) of the Act, such order to take effect on the effective date of the section in Subpart E of this part which identifies the substance.

(i) The person is operating under the terms of a consent order issued under section 5(e) of the Act applicable to that person. If a provision of such section 5(e) order is inconsistent with a specific significant new use identified in Subpart E of this part, abiding by the provision of the section 5(e) order exempts the person from submitting a significant new use notice for that specific significant new use.

12. By adding a new § 721.47 to read as follows:

§ 721.47 Conditions for research and development exemption.

(a) A person who manufactures, imports, or processes a chemical substance identifies in Subpart E of this part for a significant new use identified in Subpart E of this part is not subject to the notification requirements of § 721.25 if the following conditions are met:

(1) The person manufactures, imports, or processes the substance for the significant new use in small quantities solely for research and development.

(2) The manufacturer, importer, or processor notifies all persons in its employ or to whom it directly distributes the chemical substance, who are engaged in experimentation, research, or analysis on the chemical substance, including the manufacture, processing, use, transport, storage, and disposal of the substance associated with research and development activities, of any risk to health, identified under paragraph (b) of this section, which may be associated with the substance. The notification must be made in accordance with paragraph (c) of this section.

(3) The chemical substance is used by, or directly under the supervision of, a technically qualified individual.

(b)(1) To determine whether notification under paragraph (a)(2) of this section is required, the manufacturer, importer, or processor must review and evaluate the following information to determine whether there is reason to believe there is any risk to health which may be associated with the chemicals substance:

(i) Information in its possession or control concerning any significant adverse reaction by persons exposed to the chemical substance which may reasonably be associated with such exposure.

(ii) Information provided to the manufacturer, importer, or processor by a supplier or any other person concerning a health risk believed to be associated with the substance.

(iii) Health and environmental effects data in its possession or control concerning the substance.

(iv) Information on health effects which accompanies any EPA rule or order issued under section 4, 5, or 6 of the Act that applies to the substance and of which the manufacturer, importer, or processor has knowledge.

(2) When the research and development activity is conducted solely in a laboratory and exposure to the chemical substance is controlled through the implementation of prudent laboratory practices for handling chemical substances of unknown toxicity, and any distribution, except for purposes of disposal, is to other such laboratories for further research and development activity, the information specified in paragraph (b)(1) of this section need not be reviewed and evaluated. (For purposes of this paragraph (b)(2), a laboratory is defined as a contained research facility where relatively small quantities of chemical substances are used on a pro-production basis, and where activities involve the use of containers for reactions, transfers, and other handling of substances designed to be easily manipulated by a single individual).

(c)(1) The manufacturer, importer, or processor must notify the persons identified in paragraph (a)(2) of this section by means of a container labeling system, conspicuous placement of notices in areas where exposure may occur, written notification to each person potentially exposed, or any other method of notification which adequately informs persons of health risks which the manufacturer, importer, or processor has reason to believe may be associated with the substance, as determined under paragraph (b)(1) of this section.

(2) If the manufacturer, importer, or processor distributes a chemical substance manufactured, imported, or processed under this section to persons not in its employ, the manufacturer, importer, or processor must in written form:

(i) Notify those persons that the substance is to be used only for research and development purposes.

(ii) Provide the notice of health risks specified in paragraph (c)(1) of this section.

(3) The adequacy of any notification under this section is the responsibility of the manufacturer, importer, or processor.

(d) Quantities of the chemical substance, or of mixtures or articles containing the chemical substance, remaining after completion of research and development activities may be:

(i) Disposed of as a waste in accordance with applicable Federal, State, and local regulations, to the extent the disposal activity is not identified as a significant new use for the substance in Subpart E of this part, or

(2) Used for a commercial purpose, to the extent the use is not identified as a significant new use of the substance in Subpart E of this part.

(e)(1) Persons who manufacture, import, or process a chemical substance under this section must retain the following records:

(i) Copies of or citations to information reviewed and evaluated under paragraph (b)(1) of this section to determine the need to make any notification of risk.

(ii) Documentation of the nature and method of notification under paragraph (c)(1) of this section including copies of any labels or written notices used.

(iii) Documentation of prudent laboratory practices used instead of notification and evaluation under paragraph (b)(2) of this section.

(iv) The names and addresses of any persons other than the manufacturer, importer, or processor to whom the substance is distributed, the identity of the substance, the amount distributed, and copies of the notifications required under paragraph (c)(2) of this section.

(2) [Reserved.]

(Approved by the Office of Management and Budget under control number 2070-0012.)

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